

To: Beck, Nancy[Beck.Nancy@epa.gov]
From: Pat Quinn
Sent: Tue 5/16/2017 4:53:41 PM
Subject: FW: P&G/ Clorox/ RB Proposal To Exempt FDA Approved Flavoring Ingredients as approved Fragrance Ingredients for Antimicrobial Food Contact Pesticides---EO 13777
[EPA Docket EPA-HQ-OA-2017-0190.pdf](#)
[FSF Position Paper 5-15-2017 EO 13777.pdf](#)

Nancy, how is week 3 !!??

I'm not sure if we have spoken of my Innovation Reform Group , comprised of Clorox, P&G and Reckitt Benckiser ? I serve as the consultant/ executive director; we have worked together since 2001 on process and policy reform issues collaboratively with OPP that improve certainty, predictability and timeliness of OPP decisions. It has been one of my most satisfying professional experiences.

The attached proposal was submitted yesterday in response to EO 13777. We are putting forward the idea of a blanket exemption from tolerance requirements for about 1000 ingredients reviewed and approved by FDA. These are flavoring ingredients at FDA—approved as direct food additives. The same materials are utilized in the fragrance industry.

Typically, finished fragrances are about 0.25-0.5% of an antimicrobial product, and composed of 20-100 fragrance ingredients. Residential and commercial customers demand fragranced products for use in kitchen and other food use settings.

Recent changes in OPP policy will significantly impact the availability of fragrances for food surface contact use. Previously, OPP recognized that a Potable Water Rinse (PWR) when used following use of a sanitizer in the kitchen, removed all residue --- thereby negating the need for a tolerance under FIFRA or approval as a food use inert. That policy has changed --now worst case residues are assumed , meaning that thousands of inert ingredients (surfactants, chelators, fragrances) will now require costly tolerance petitions to be filed with OPP.

These would be reviewed by the already under resourced Inerts Branch. With about 1500 fragrance ingredients now used in FIFRA approved products , the PRIA tolerance fees (\$27,000/ petition) and EPA resource demands will be overwhelming. More importantly, about 1000 of the 1500 ingredients have been thoroughly vetted by FDA's expert panels and are routinely and safely consumed as direct food additives now.

Further review by EPA of these same materials used at de minimis concentrations would be duplicative and a waste of Federal Government resources –and the regulatory burden on industry would be enormous. Finally, the opportunity for risk reduction or public health protection simply isn't present –and the tolerance review process will take years.

OGC may argue that EPA's FQPA obligations are different than FDA's FFDCA obligations, but that is not at all clear –and should not be a determinative factor.

I would like your thoughts on how we might work with you and the OPP affected staff on this to move the idea forward. I realize that you must be drinking from a fire hose right now but wanted to plant this seed while it was fresh in my mind.

Hope you are enjoying the new challenge –and that we can see each other soon, Pat